

REMARKS

Disposition of the Claims

Claims 1, 6-8, 24, 28, 30-32, 40-44, 52 and 58-62 are presently pending. Of these, Claims 31, 32, 40-44, 60 and 61 are withdrawn from consideration. Claims 59-62 are new.

Support for Claim Amendments

Support for the amendments to Claims 1, 31 and 58 and new Claim 62 may be found throughout the specification, including, for example, page 17 (lines 3-13, including for example nucleic acid fragments between 15 and 75 nucleotides), Table 1 bridging pages 33-34, and the claims as originally filed. In particular, the specification discloses that the recited nucleic acid can comprise a fragment of 15 or more nucleotides of SEQ ID NO:1, which includes the sequence of SEQ ID NO:3. The specification also discloses that SEQ ID NO:2-9 can be used as primers to amplify SEQ ID NO:1. Thus, the specification also discloses embodiments of fragments that necessarily encompass 15 or more nucleotides of SEQ ID NO:3.

Support for the amendment to Claim 28 can be found, for example, on page 26 (lines 25-28), page 27 (lines 1-5), Example 4 (pages 34-35) and Example 8 (page 38). Support for new Claims 59-62 is evident through the specification including, for example, Claims 31-33 and 53 as filed, page 26 (lines 25-28), page 27 (lines 1-5), Example 2 (pages 33-34), Example 4 (pages 34-35) and Example 8 (page 38).

The following addresses the substance of the Office Action.

Written Description

Claims 1, 6-8, 24, 28, 30, 52 and 58 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. In particular, the Examiner indicated that the limitation “comprising at least 19 consecutive nucleotides” was not present in the Specification at the time of filing.

Without acquiescing, the limitation “comprising at least 19 consecutive nucleotides of SEQ ID NO: 1” has been removed from the claims. Claims 1, 31 and 58 are amended to relate to “An isolated nucleic acid comprising a sequence as defined in SEQ ID NO: 1 or a fragment thereof, wherein the fragment comprises a sequence of 15 or more nucleotides from SEQ ID NO: 3.” Referring to the Specification as filed at page 17, lines 3-10, the disclosed isolated nucleic acid molecules include SEQ ID NO: 1 and fragments thereof having between about 15 to about

725 nucleotides in length. Referring to page 17, lines 11-13, an example of a fragment of SEQ ID NO: 1 is SEQ ID NO: 3, which is also disclosed at Table 1 (i.e., JAS-52). Thus, the specification discloses fragments of SEQ ID NO: 1 that comprises 15 or more nucleotides from SEQ ID NO: 3. Accordingly, the amendments are supported by the specification and do not add new matter.

In view of the amendments to the claims and the preceding remarks, the Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Indefiniteness

Claim 52 was rejected under 35 U.S.C. § 112, second paragraph as being incomplete for omitting essential steps. In particular, the Patent Office indicated that the omitted steps are: decision of diagnosis directly linked to the presence of hybridization. The preamble of Claim 52 is amended to recite “A method of diagnosing infection or lack of infection...” and step (d) is amended to recite “diagnosing infection of said subject based on the presence of said hybridization or diagnosing lack of infection based on the absence of said hybridization.” A similar amendment has been made to Claim 28.

Anticipation

Claims 1, 24, 28, 30, 52 and 58 were rejected under 35 U.S.C. § 102(b) as being anticipated by Pestka et al. (WO 2001/016153). In particular, the Examiner noted that SEQ ID NO: 1 of Pestka et al. aligns with SEQ ID NO: of the instant application, and that there are a plethora of sequences comprising at least 19 consecutive nucleotides of SEQ ID NO: 1 of the instant application.

However, in light of the amendments to the claims, the Applicant respectfully requests withdrawal of this rejection. As noted above, Claims 1, 31 and 58 are amended to relate to “An isolated nucleic acid comprising a sequence as defined in SEQ ID NO: 1 or a fragment thereof, wherein the fragment comprises a sequence of 15 or more nucleotides from SEQ ID NO: 3. The IL-10 sequence provided in Pestka et al. differs from SEQ ID NO: 1 in the claims as shown in the sequence alignment provided under Item 8 of the Office Action dated June 8, 2010. The differences between the two DNA sequences shown in the alignment can be summarized as follows:

- (i) a 28 nucleotide segment at the N-terminus of SEQ ID NO: 1 that is absent in the Pestka et al. sequence;
- (ii) a 3 nucleotide insertion at residues 140-143 of SEQ ID NO: 1 that is absent in the Pestka et al. sequence;
- (iii) an 76 nucleotide insertion commencing at residue 245 of the Pestka et al. sequence which is absent in SEQ ID NO: 1
- (iv) point mutations at positions 62, 354 and 447

As shown in the attached Exhibit, the fragment of SEQ ID NO: 1 defined by SEQ ID NO: 3 is not a component of the sequence taught in Pestka et al. The Exhibit shows SEQ ID NO: 1 with differences to the Pestka et al. sequence indicated in bold type and underlined. The fragment of SEQ ID NO: 1 defined by SEQ ID NO: 3 falls entirely outside the Pestka et al. sequence as shown in the attached Exhibit. Accordingly, the subject matter of Claims 1, 24, 28, 30, 52 and 58 is novel over the IL-10 sequence taught by Pestka et al.

New Claim 60 recites a method of detecting a latent infection by a herpesviridae virus by detection of a nucleic acid according to Claim 1. A significant difference in comparison with the IL-10 homologue disclosed in Pestka et al. is that Applicant's viral IL-10 homologue is expressed during the latent phase of infection and during the productive phase of infection whereas the sequence disclosed by Pestka et al. has not been reported to be expressed during latency. Moreover, the Applicant's viral IL-10 homologue sequence translates to a 139 amino acid polypeptide product having a unique 12 amino acid at its C-terminus. This differs from the IL-10 sequence of Pestka et al., which encodes a polypeptide of 175 amino acids that does not have the unique 12 amino acid at its C-terminus.

In view of the reasons set forth above, the Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure,

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including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants' amendments to the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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